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10/576,297

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EXAMINER

GORDON, BRIAN R

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/576,297	Applicant(s) KORPELA ET AL.	
	Examiner Brian R. Gordon	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8-4-10.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-10 in the reply filed on August 4, 2010 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Specification

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for binding a component in a sample to magnetic microparticles when the sample is in contact with the magnet microparticles, does not reasonably provide enablement for binding any components in a sample to the magnetic microparticles when the sample is never placed in contact with the microparticles. The specification does not enable any person skilled in the art to which

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it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The preamble of the claim recites the purpose of the method is for binding a sample component to microparticles. However, the method of claimed 1 only involves two broad steps, change of solutions and mixing. The two steps do not support the assertion of the preamble. The steps are not related to the microparticles and binding a sample component to the microparticles.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

8. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: at least providing a vessel and placing magnetic microparticles in a vessel and placing a sample including a desired component in the vessel in contact with the microparticles.

It is unclear how one change of solutions and one mixing is related to binding a sample component. The claims as drafted are ambiguous and unclear. The claims do not clearly define the steps or order in which the steps are performed.

It is unclear how the claim can exclude moving the microparticles to another vessel, when no prior location has been established for the microparticles.

It is unclear what is the relationship of "one change of solutions" to binding components of a sample. What is the relationship of the sample and solutions? Where are the sample and solutions located? What is meant by change of solutions? Does this mean moving solutions from one location to another, discarding solutions and replacing the solutions with more of the same solutions or some other substance? Where does the change occur?

It is unclear what is meant by "one mixing". What is mixed? Where and how does the mixing occur? How is the mixing related to binding a sample component?

The "wherein" claims directed to the desired sample component is not further limiting of the method. The clause does not add any additional step. Furthermore, the sample is not required to be involved in the two steps. Therefore, the sample and components thereof are not required for the method.

It is unclear if each of the dependent claims is intended to add further steps to that of claim 1 or if the claims are an attempt to further define the steps of claim 1. The claims in general are drafted using past-tense language as if the events have already occurred.

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As to claim 2 it is unclear if (a) is meant to be an additional step to that of claim 1. If so, when does this occur relative to steps of claim 1? Does it occur prior to the steps of claim 1, after the steps of claim 1, etc? Where does the treating occur? It is unclear what constitutes "treated".

As to (b) and (c) it is unclear when and where the steps occur relative to the steps of claim.

Paragraph (c) recites a solution (23), while claim 1 recites solutions (23). It is unclear if there is a difference between solutions (23) and solution (23). What is the difference? What is the relationship between the two different recitations? The different recitations are confusing. Where are the solutions (23) located and where is the solution (23) located? How can solutions (a plurality) be the same as a single solution? This is applicable any other claims that also recites solution/solutions.

As to claim 3, it is unclear what is meant by "homogenized from the inner surface of the vessel". Is applicant attempting to claim an additional step of homogenizing the microparticles in a solution in the vessel? What does "from the inner surface of the vessel" contribute to homogenizing? When does the step occur relative to the previously claimed steps?

Claim 3(c) contradicts claim 1. Claim 1 excludes moving the microparticles to another vessel. However 3(c) states the method involves moving the microparticles to another vessel.

Claims 3-4, 7 recite the limitation "the inner surface of the vessel". There is insufficient antecedent basis for this limitation in the claim. (See claim 3, line 4 and claim 4, line 5).

As to claim 4, it is unclear how the claim further limits the method of claim 1. Paragraph 4(a) is directed to the structure of a magnetic tool that has not been recited as being involved in either of the two steps of claim 1. Furthermore is unclear what defines "a whole procedure". Claim 1 is directed to a method that includes two broad steps. It has not been established that the method excludes any other steps. A single step can be considered a whole procedure if one chooses to label it as such. Applicant has not previously defined what constitutes a whole procedure.

It is unclear how "washing solutions" are related to the method and what is the relationship of the washing solutions to the previously recited solutions of claim 1. How can solutions be changed in or in separate vessels? What does applicant mean by "changed"? How are separate vessels related to the method? When does the change occur relative to the method steps of claim 1?

Claim 5 recites the limitation "the solution" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 5 recites the limitation "the solution that contains the microparticles" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Claim 1 recites solutions. How does the variation of solutions of claim 5 relate to the solutions of claim 1? It is unclear what is the difference between the three different recitations. Furthermore, it is unclear how claim 5 further limits the method of claim 1. Is

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the claim directed to additional steps or is the claim an attempt to further limit the two steps of claim 1.

As to claim 5, it is unclear how, when, and where the stretching and releasing occur relative to the steps of the method. It is further unclear what "in the solution" references. What solution? As stated above different versions of the word "solution" appears in claims and 5.

Claim 1 broadly references mixing. The claim does not state what is mixed or when and how the mixing is performed. As such, it is unclear how claim 6 relates to claim 1. See also the previous rejection concerning claim 5, which is also applicable to claim 6.

Claim 7 is a combination of claims 3-5. As such, the previous rejections of claims 3-5 are also applicable to claim 7.

As to claims 8-10, it is unclear what is the relationship of "a solution" of claim 8 and the solutions of claim 1. Furthermore it is unclear when the collection (and further references to events) occurs relative to the steps of claim 1.

Claim 9 is also a combination of previous recitations which have been addressed. Applicant should take note of the examiner's prior rejections. It is unclear how the claim further limits the method of claim 1. When did each of the actions of the claim occur relative to the method steps of claim 1?

As to claim 10, it is unclear how the claim further limits the method of claim 1. It is unclear if the filter is located in or on an exterior bottom of the vessel.

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It should be noted the use of reference numerals within the claims do not further limit the scope of the claim.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Korpela, WO 9626011 A1.

Korpela discloses an apparatus and a method for treating magnetic particles (24). The particles are of the kind defined as microparticles in the invention (see abstract and page 13, line 17- line 20). The microparticles can be paramagnetic, supermagnetic, and ferromagnetic (page 27, line 1). Mixing, separation and cleaning of the particles take place in a container without moving the particles out of said container (see esp. figures 5a-f, page 18, line 27- page 19, line 21, page 8, line 17- line 20 and page 21, line 29- line 32). The device employs magnetic tool (4, 30) that stretches the

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elastic membrane (2') into the container. The magnetic tool attracts the microparticles when inserted in the container. The tool can also include a sleeve (page 18, line 23).

11. Claims 1-2 are rejected under 35 U.S.C. 102(e) as being anticipated by Siddiqi, US 2006/0207944.

Siddiqi discloses an apparatus and method for carrying out the affinity separation of a target substance from a liquid test medium by mixing magnetic particles having surface immobilized ligand or receptor within the test medium to promote an affinity binding reaction between the ligand and the target substance. The test medium with the magnetic particles in a suitable container is removably mounted in an apparatus that creates a magnetic field gradient in the test medium. This magnetic gradient is used to induce the magnetic particles to move, thereby effecting mixing. The mixing is achieved either by movement of a magnet relative to a stationary container or movement of the container relative to a stationary magnet. In either case, the magnetic particles experience a continuous angular position change with the magnet. (Abstract). The magnetic separation process typically involves mixing the sample with paramagnetic particles in a liquid medium to bind the target substance by affinity reaction. (paragraph 0010). Figures 5A-F should one embodiment of the steps of the process. As seen in Figure 5B the microparticles are bound to the inner wall of the container. FIG. 5c shows the apparatus during a washing step. In this step, an outlet tube 59a aspirates the supernatant test medium and an inlet tube 59b adds a suitable wash solution into the test tube 23. The magnetic particles 58 are then mixed in the wash solution. The old

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wash solution is aspirated and new clean solution may be added. The washing step may be repeated as many times as required. (paragraph 102).

12. Claims 1-2 are rejected under 35 U.S.C. 102(e) as being anticipated by Gordon et al. US 2004/0047765.

Gordon et al discloses a process for separation and purification via processing under influence of a magnetic field. To this end, samples are mixed with ferromagnetic or paramagnetic (collectively, "magnetic") beads, e.g., of the type available from Dynal, Inc., that bind to selected components in the samples. (paragraph 0310). The pipetters and contained samples are placed within a magnetic field, e.g., via placing small, powerful magnets against, surrounding or in close proximity to the outsides of the pipetter chambers. This entrains the magnetic beads and components to which they are bound, attracting and immobilizing them against the inner walls of the chambers. Separation may be accelerated by reciprocating the nanopipetter plungers back and forth so that all portions of the samples pass in close proximity to the magnet or are otherwise exposed to the magnetic field. Care, however, should be taken not to disrupt the beads already entrained by the magnets. (paragraph 0311). The reference further discloses mixing, washing, and changing liquids in the chamber. (paragraphs 0312-0316, see Figure 15).

13. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Korpela, US 6,468,810.

Korpela discloses a device and method for purifying liquids that includes mixing, washing, and changing liquids. The method involves the use of paramagnetic,

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superparamagnetic or ferromagnetic microparticles 12 and a magnet that manipulates the microparticles. The magnet's surface is separated from the microparticles either with the aid of an extendable membrane or shapable membrane or magnet coating so that the membrane or coating does not essentially weaken the magnetic field directed at the microparticles. (column 4, lines 52-56). The magnetic particles do not accumulate directly onto the metallic surface of the magnet but around the protective membrane or coating surrounding the magnet. (column 7, lines 31-49). The magnets of the device for transfer have sleeves and a common membrane. (column 8, lines 7-9).

Microparticles can be transferred to the wash liquid in well 62 even directly from a separate storage vessel. In differing methods for processing of samples various proceedings according to each method may be realised in the wells of plate 56, such as stages for heating, cooling, mixing, measuring (analytical methods) and dosage of reagents.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Holtlund; Jostein et al.; Self; Brian Austin et al.; Rundt; Kenneth et al.; Adourian, Aram S. et al.; Srivastava; Alok et al.; Holtlund; Jostein et al.; Siddiqi; Iqbal Waheed; Blecka; Lawrence et al.; Hardman; Clayton M. et al.; Kreuwel; Hermanus Johannes Maria et al.; and Anderson; N. Leigh disclose method and devices for magnetic microparticle separations.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, 1st Fri. Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian R Gordon/
Primary Examiner
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